FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 2, 2019

Matthew Dailey
FCI Milan Low Security Prison
4004 East Arkona Road
Milan, MI 48160

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-3310

Dear Mr. Dailey:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order under section 306(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(b)(1)(D)) debarring you for a period of ten years from importing or offering for import any drug into the United States. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), of one felony count under federal law for introducing misbranded drugs into interstate commerce and one felony count of importing merchandise contrary to law. The factual basis supporting both felony convictions, as described below, is conduct relating to the importation into the United States of any drug or controlled substance (21 U.S.C. § 335a(b)(3)(C)). This letter also offers you an opportunity to request a hearing on this proposal and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On May 8, 2019, you were convicted as defined in section 306(l)(1) of the Act (21 U.S.C. § 335a(l)(1)(B)), in the United States District Court for the Eastern District of Michigan, when the court accepted your plea of guilty and entered judgment against you for the offense of Introducing Misbranded Drugs Into Interstate Commerce in violation of 21 U.S.C. § 331(a) (section 301(a) of the Act) and Importing Merchandise Contrary to Law in violation of 18 U.S.C. § 545. The underlying facts supporting this conviction are as follows:

As contained in the stipulation of facts incorporated into your Plea Agreement, filed on January 8, 2019, from on or about March 2011 through November 2016, you imported hundreds of shipments of kratom into the United States. To evade the lawful regulatory authority of the FDA, you instructed your foreign suppliers to label shipments of bulk kratom with materially false statements that described the kratom as "incense," "paint pigment," and other substances not regulated by the FDA. You also provided the FDA (sometime through import brokers) materially false written descriptions of your bulk kratom imports. After receiving the kratom you then apportioned bulk shipments of kratom into smaller portions and repackaged the kratom into smaller plastic bags at a location not registered as a facility that manufactures, prepares, propagates, compounds and processes drugs. You then sold kratom products to hundreds of consumers through the United States through a website you managed. The labeling of your kratom products did not include any directions for use, such as indications, dosage instructions, methods of administration, or contraindications. In selling your kratom product, you intended that consumers use your kratom products as a "drug" within the meaning of section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)). Specifically, you intended that consumers use the kratom you imported to treat and mitigate diseases, including but not limited to chronic pain, fibromyalgia, opiate withdrawal, and Lyme disease, and to affect the structure and function of the human body by taking the kratom products as substitutes for drugs of abuse and prescription pills. As stated in the Stipulation of Facts, your actions were in violation of 21 U.S.C. § 331(a) (section 301(a) of the Act) and 18 U.S.C. § 545.

FDA's Finding

Section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) permits FDA to debar a person from importing or offering

for import into the United States a drug. An individual who has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance may be subject to debarment, as set forth in section 306(b)(3)(C) of the Act (21 U.S.C. § 335a(b)(3)(C)). FDA finds that the felony counts for which you were convicted were for conduct relating to the importation of any drug or controlled substance into the United States because you illegally imported kratom, a misbranded drug, for repackaging, sale, and distribution to U.S. consumers in violation of 21 U.S.C. § 331(a) (section 301(a) of the Act) and 18 U.S.C. § 545.

The maximum period of debarment for each felony under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is not more than five years, and debarment periods may run consecutively or concurrently. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration, where applicable, in determining the appropriateness of and period of permissive debarment for an individual:

1. the nature and seriousness of any offense involved,

2. the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

3. the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including . . . discontinuation of the distribution of suspect drugs, . . . full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) . . . and any other actions taken to substantially limit potential or actual adverse effects on the public health,

4. whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

5. whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated new drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

6. prior convictions under the Act or under other Acts involving matters within the jurisdiction of the FDA.

The FDA has determined that three of these factors are applicable for consideration:

1. Nature and seriousness of any offense involved.

As described in detail above, you were convicted of one felony count under Federal law for introducing misbranded drugs, kratom, into interstate commerce and one felony count of importing merchandise contrary to law. You imported kratom on numerous occasions and you knowingly took steps to conceal your actions by instructing your foreign suppliers to label shipments of bulk kratom with materially false statements in order to evade FDA regulators. In addition, you sold kratom products to hundreds of consumers through the United States with the intention that consumers use your kratom products as a "drug" within the meaning of section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)). However, you did not provide those consumers any directions for use, such as indications, dosage instructions, methods of administration, or contraindications. As such, you put the public health at risk. There are currently no FDA-approved kratom drug products. Consumption of kratom can cause serious side effects, including seizures, liver damage, and withdrawal symptoms. The Agency finds that your conduct seriously undermined FDA's regulation of drugs. Accordingly, the FDA concludes that the nature and seriousness of the offense involved supports the maximum possible period of debarment.

2. **Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved.**

In determining the period of a debarment, FDA is also to consider the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved, including, among other things, discontinuation of the distribution of suspect drugs, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing), and any other actions taken to substantially limit potential or actual adverse effects on the public health. The FDA is unaware of any steps you took to discontinue the importation and distribution of kratom or mitigate the impact on the public of your actions, which undermined the integrity of FDA's regulation of the importation of drugs into the United States, resulting in the introduction of misbranded drugs into interstate commerce.

As detailed above, the facts show that you displayed a willful disregard the regulatory requirements for drug products, including the registration requirements for drug manufacturers and requirements for drug importation. Accordingly, FDA will consider this a negative factor. FDA concludes that the failure to take any steps to mitigate the potential impact on the public supports the maximum possible period of debarment.

3. **Prior convictions under the Act or involving matters within the jurisdiction of FDA.**

FDA is unaware of any prior criminal convictions involving matters within the jurisdiction of FDA. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA concludes that the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a ten-year period of debarment. FDA therefore proposes to issue an order under section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) debarring you from importing drugs or offering drugs for import into the United States for a period of ten years.

In accordance with section 306 of the Act (21 U.S.C. § 335a) and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction supports your debarment under section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2019-N-3310 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You also may notify FDA that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to FDA in accordance with section 306(c)(2)(B) of the Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Division of Enforcement, Office of Regulatory Affairs pursuant to FDA Staff Manual Guide 1410.35.

Sincerely,

/s/
Scott J. MacIntire
Director
Division of Enforcement
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U. S. Food and Drug Administration